

## AMENDMENTS TO THE CLAIMS

1-6. (Cancelled).

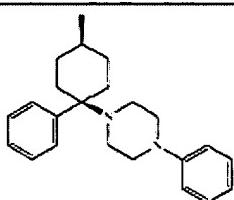
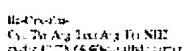
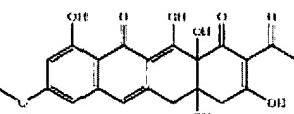
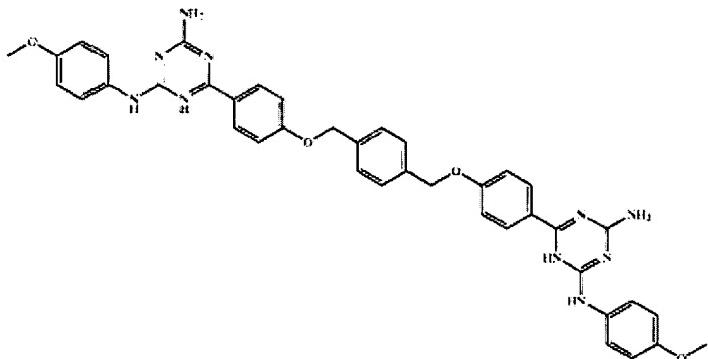
7. (Currently Amended) A method according to claim 13-14 wherein the medicament is administered by mouth.

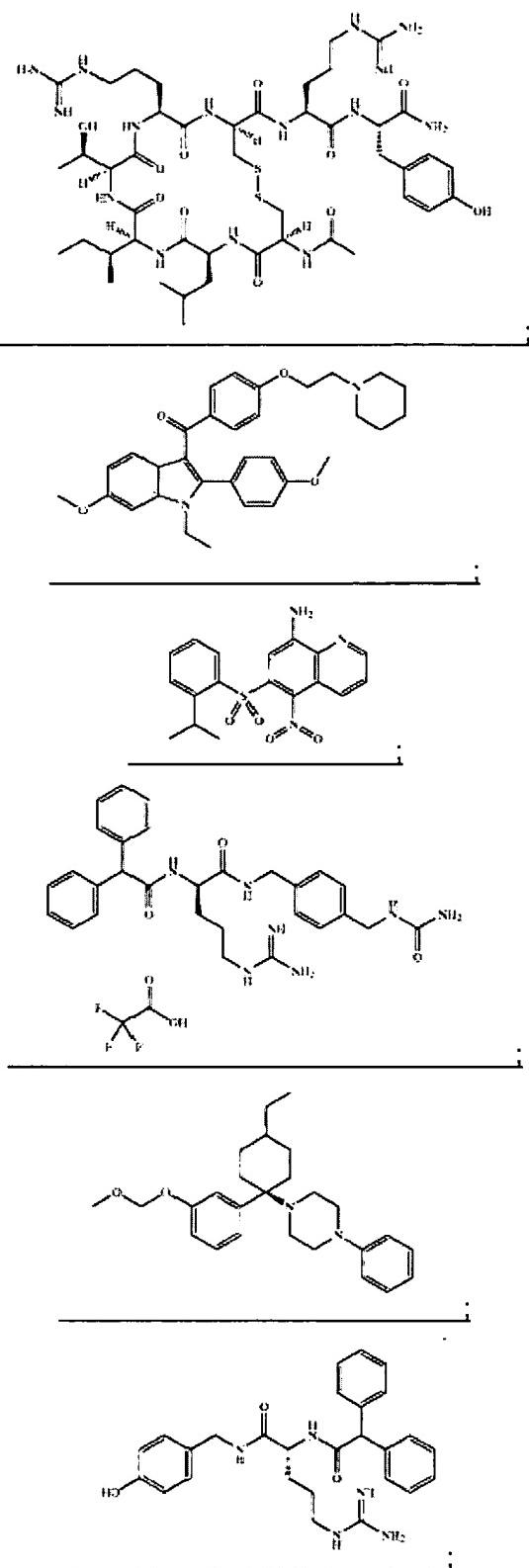
8. (Cancelled)

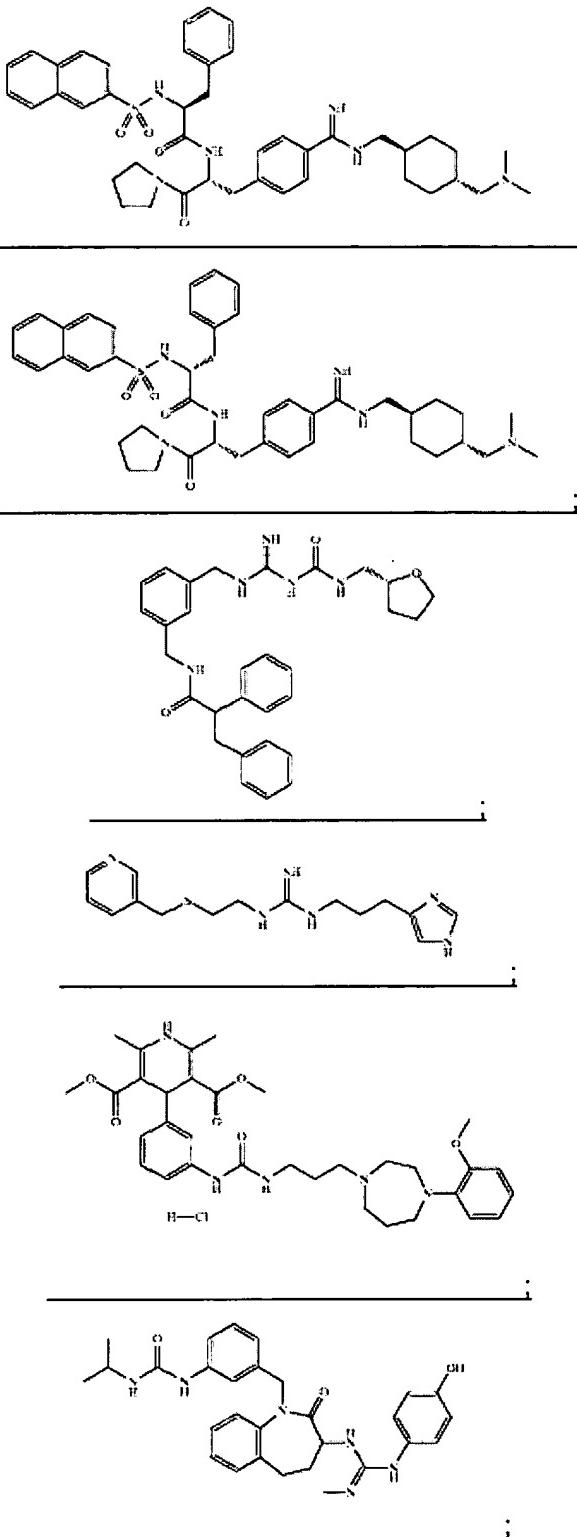
9. (Currently Amended) A method according to claim 13-44 wherein said NPY and/or NPY Y1 inhibitor is administered before and/or during sexual arousal.

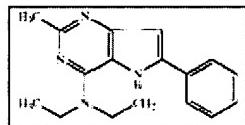
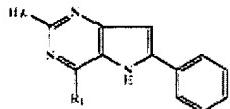
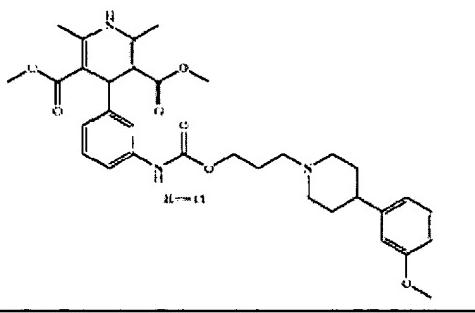
10. (Cancelled)

11. (Currently Amended) A pharmaceutical composition for use in the treatment of male erectile dysfunction comprising an inhibitor of a neuropeptide Y (NPY), selected from the group consisting of:

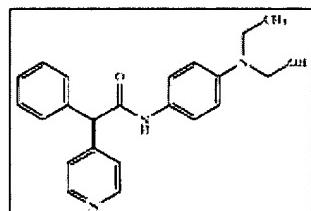
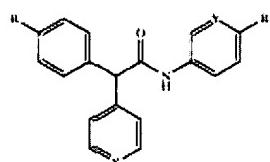




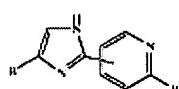




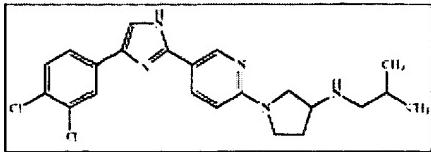
$R_1 = SR, R, CO-H, p$ -nitrophenyl, morpholin-4-yl  
 $R_2 = H, Ph$   
 $R_3 = NH_2, CH_3CH_2Cl, Cl, 4$ -methyl-piperazine-1-yl, allyl, Ph



$R = R_1, F$   
 $R_1 = N^+H_2^+, p$ -nitro-*p*-toluidine, 2,6-Me<sub>2</sub>cyclodextrin  
 $X, Y = CH_2N$



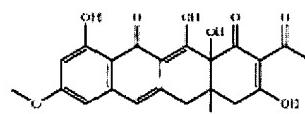
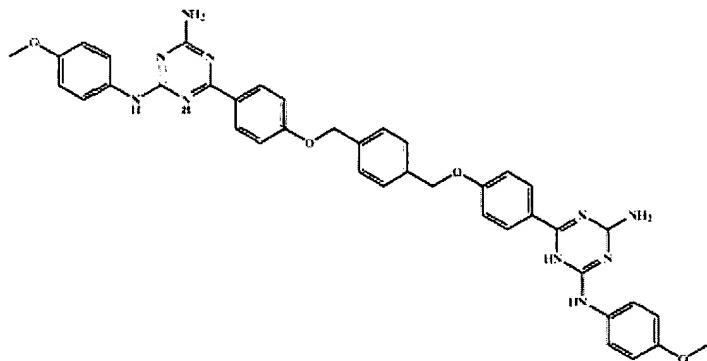
; and



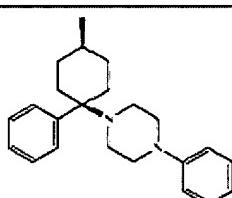
R = *tert*-butyl  
R<sub>1</sub> = 2-(2-chlorophenyl)-  
2-(2-methylpropyl)-1-  
pyrrolidine

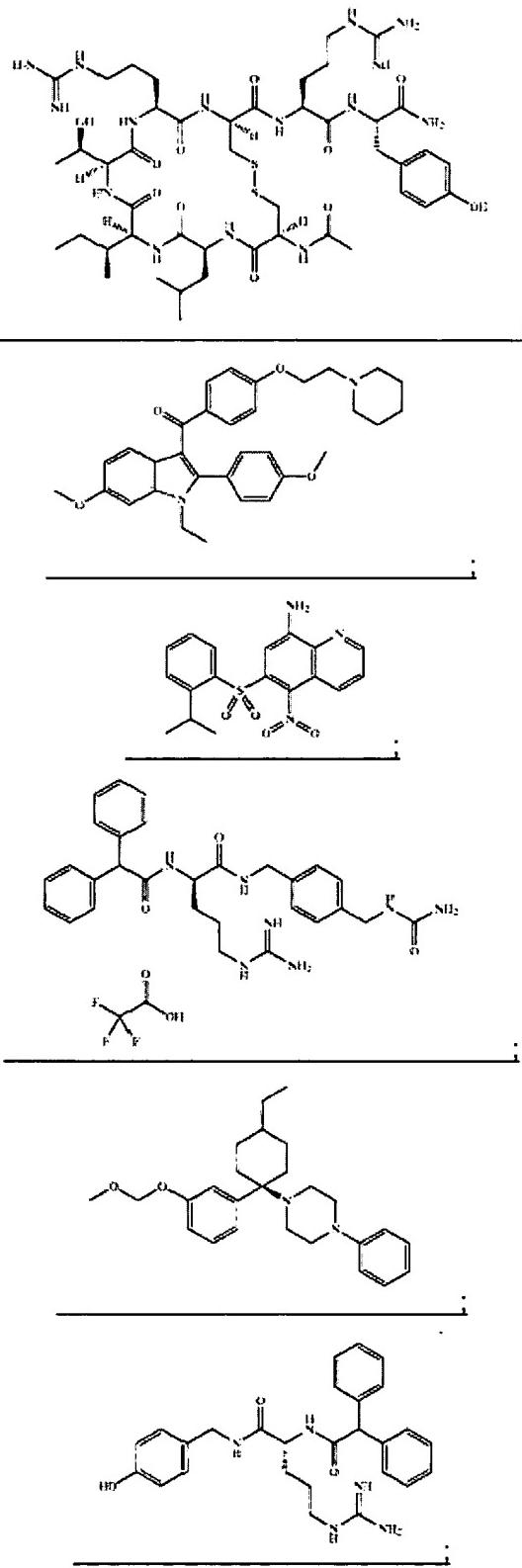
which inhibitor when in use is selective for an NPY associated with male genitalia; wherein the inhibitor is admixed with a pharmaceutically acceptable carrier, diluent or excipient

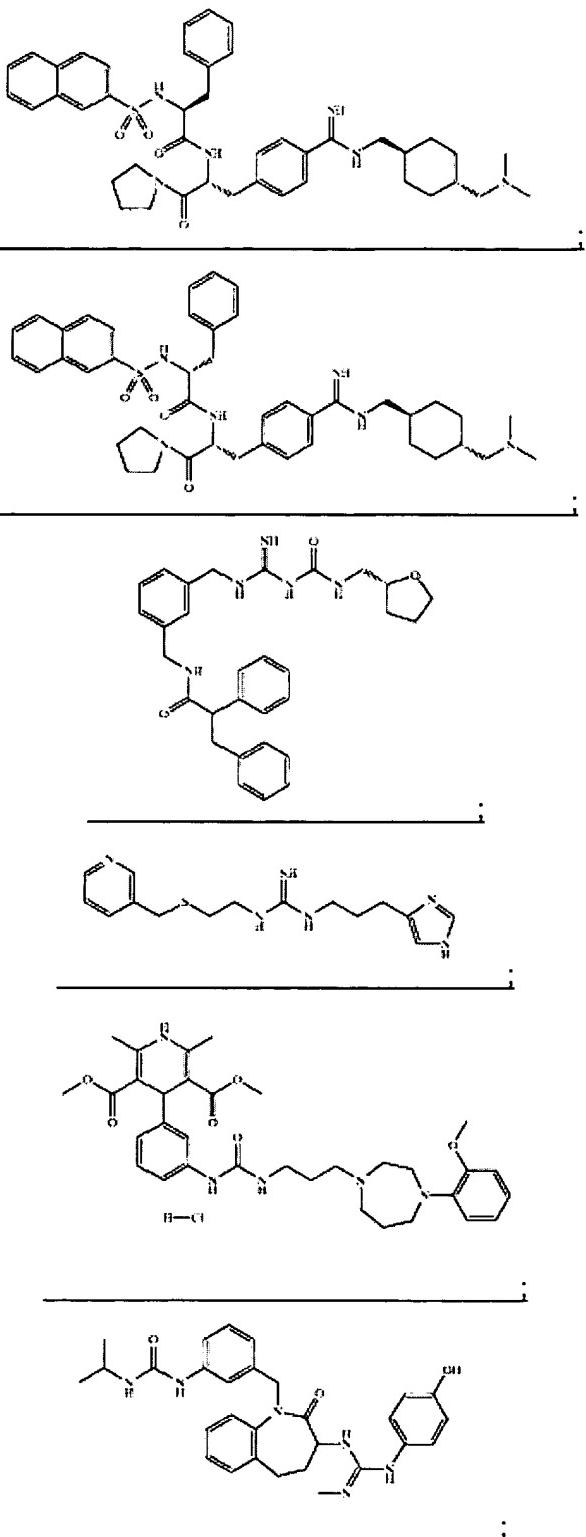
12. (Cancelled).
13. (Currently Amended) A method of treating or preventing male erectile dysfunction in a human or animal which method comprises administering to an individual effective amount of an NPYi selected from the group consisting of,

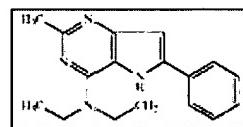
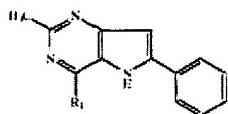
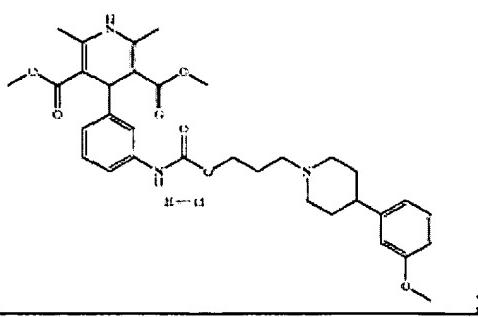


11-Cyclohexa-  
C<sub>17</sub>-20-A<sub>2</sub>-22-A<sub>2</sub>-D<sub>1</sub>-N(2)  
cyclo(-C<sub>17</sub>-20-A<sub>2</sub>-22-A<sub>2</sub>-D<sub>1</sub>-N(2))

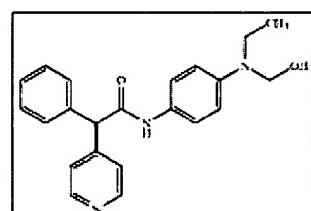
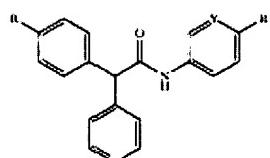




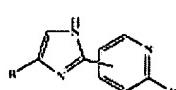




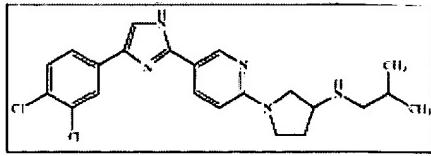
R<sub>1</sub> = NR<sub>2</sub>R<sub>3</sub>C(=O)H, piperazine morphine  
R<sub>2</sub> = H, Me  
R<sub>3</sub> = NH<sub>2</sub>, CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>4-(Methylpenicillloyl)alkyl, Ph



R<sub>1</sub> = H, F  
R<sub>2</sub> = NF<sub>2</sub>, propenoate pyridine, 2-Mercaptobenzaldehyde  
X, Y = CH<sub>2</sub>N



; and



R<sub>1</sub>=1-(2-chlorophenyl)-  
4-(cyclopentylmethyl)-3-methylpyridine-2-carboxylate  
(1<sup>H</sup>NMR)

which NPYi when in use is selective for an NPY receptor associated with male genitalia, wherein the NPYi, is optionally admixed with a pharmaceutically acceptable carrier, diluent or excipient.

14-16. (Cancelled)

17. (Withdrawn) An assay method for identifying an agent that can be used to treat MED, the assay comprising: determining whether a test agent can directly enhance the endogenous erectile process; wherein said enhancement is defined as a potentiation of intracavernosal pressure (and/or cavernosal blood flow) in the presence of a test agent; such potentiation by a test agent is indicative that the test agent may be useful in the treatment of MED and wherein said test agent is an NPYi.

18. (Withdrawn) An assay according to claim 17 wherein said test agent is an NPY Y1.

19. (Withdrawn) An assay according to claim 18 wherein said test agent selectively inhibits NPY or NPY Y1 receptors associated with the genitalia.

20. (Withdrawn) A process comprising the steps of:

- performing an assay according to claim 18;
- identifying one or more agents capable of inhibiting NPY Y1; and
- preparing a quantity of those one or more identified agents; and wherein said agent is an NPY Y1i.

21. (Withdrawn) A process according to claim 20 wherein said process further comprises testing said one or more agents identified in step (b) for their effect on arterial blood pressure and selecting agents with no, or substantially no, effect on blood pressure.

22. (Withdrawn) An assay method for identifying an agent that can be used to treat or prevent MED, the assay comprising: contacting a test agent which has a moiety capable of inhibiting the metabolic breakdown of a peptide (preferably a fluorescent labelled peptide), said peptide being normally metabolised by NPY or NPY Y1; and measuring the activity and/or levels of peptide remaining after a fixed time (for example via fluorometric analysis); wherein the change in the level of the peptide measured by

fluorescence is indicative of the potency (IC<sub>50</sub>) of the test agent and is indicative that the test agent may be useful in the treatment of MED; and wherein said test agent is an NPYi.

23. (Withdrawn) An assay according to claim 22 wherein said test agent is an NPY Y1i.

24. (Cancelled).

25. (Withdrawn) An agent identified by the assay methods according to claim 23.

26. (Cancelled)

27. (Cancelled)

28. (Withdrawn) A diagnostic method wherein the method comprises: isolating a sample from a male; determining whether the sample contains an entity present in such an amount as to cause MED; wherein the entity has a direct effect on the endogenous erectile process in the corpus cavernosum of the male; and wherein said entity can be modulated to achieve a beneficial effect by use of an agent, and wherein said agent is an NPYi or an NPY Y1i.

29. (Withdrawn) A diagnostic composition or kit comprising means for detecting an entity in an isolated male sample; wherein the means can be used to determine whether the sample contains the entity and in such an amount to cause MED, or is in an amount so as to cause MED; wherein the entity has a direct effect on the endogenous erectile process and wherein said entity can be modulated to achieve a beneficial effect by use of an agent; and wherein said agent is an NPYi or an NPY Y1i.

30. (Withdrawn) An animal model for identifying an agent capable of treating MED, said model comprising an anaesthetised animal including means to measure changes in intracavernosal pressure and/or cavernosal blood flow of said animal following stimulation of the pelvic nerve thereof; and wherein said agent is an NPYi or an NPY Y1i.

31. (Withdrawn) An animal model according to claim 30 wherein said model further comprising means to measure arterial blood pressure of said animal.

32. (Withdrawn) An assay method for identifying an agent that can directly enhance the endogenous erectile process in order to treat MED, the assay method comprising: administering an agent to the animal model of claim 30; and measuring the change in the endogenous erectile process; wherein said change is defined as a potentiation of intracavernosal pressure (and/or cavernosal blood flow) in the animal model in the presence of a test agent as defined; and wherein said agent is an NPY Y1i.

33. (Previously presented) A method according to claim 13 wherein in addition to the treatment of male erectile dysfunction, abnormal drink and food intake disorders are also treated.

34. (Currently Amended) A The method for treating or preventing male erectile dysfunction of Claim 13 by administering a combination consisting of one or more NPYi's and further comprising one of the following auxiliary active agents to an individual:

- (i) Naturally occurring or synthetic prostaglandins or esters thereof.;
- (ii)  $\alpha$  - adrenergic receptor antagonist compounds;
- (iii) NO-donor (NO-agonist) compounds;
- (iv) Potassium channel openers or modulators;
- (v) Dopaminergic agents;
- (vi) Vasodilator agents;
- (vii) Thromboxane A2 agonists;
- (viii) CNS active agents;
- (ix) Ergot alkaloids;
- (x) Compounds which modulate the action of natriuretic factors;
- (xi) Angiotensin receptor antagonists;
- (xii) Substrates for NO-synthase;
- (xiii) Calcium channel blockers;
- (xiv) Antagonists of endothelin receptors and inhibitors or endothelin-converting enzyme;
- (xv) Cholesterol lowering agents;
- (xvi) Antiplatelet and antithrombotic agents;
- (xvii) Insulin sensitising agents;
- (xviii) L-DOPA or carbidopa;
- (xix) Acetylcholinesterase inhibitors;
- (xx) Steroidal or non-steroidal anti-inflammatory agents;
- (xxi) estrogen agonists and/or estrogen antagonists;
- (xxii) A PDE inhibitor;
- (xxiii) An NEP inhibitor;
- (xxiv) Vasoactive intestinal protein (VIP), VIP mimetic, VIP analogueone or more of a  $\alpha$ -adrenoceptor antagonist with VIP combination;
- (xxv) A melanocortin receptor agonist or modulator or melanocortin enhancer;
- (xxvi) A serotonin receptor;

- (xxvii) A testosterone replacement agent, testosternone, dihydrotestosterone or a testosterone implant;
- (xxviii) Estrogen, estrogen and medroxyprogesterone or medroxyprogesterone acetate (MPA), or estrogen and methyl testosterone hormone replacement therapy agent;
- (xxix) A modulator of transporters for noradrenaline, dopamine and/or serotonin;
- (xxx) A purinergic receptor agonist and/or modulator;
- (xxxi) A neurokinin (NK) receptor antagonist;
- (xxxii) An opioid receptor modulator;
- (xxxiii) An agonist or modulator for oxytocin/vasopressin receptors,;
- (xxxiv) Modulators of cannabinoid receptors;
- (xxxv) A bombesin receptor antagonist;
- (xxxvi) A SEP inhibitor; or
- (xxxvii) An agent capable of modulating the activity of an intermediate conductance calcium-activated potassium ( $IK_{Ca}$ ) channel in the sexual genitalia of an individual.

35. (Currently Amended) The A-method of Claim 34 treating or preventing male erectile dysfunction by administering a combination consisting of one or more NPYi's and wherein the auxiliary active agent administered is one or more PDEi's to an individual.

36. (Cancelled).

37. (Currently Amended) A method according to claim 35 36 wherein said PDEi is a PDE5i.

38. (Previously presented) A method according to claim 37 wherein the medicament is administered by mouth.

39. (Withdrawn) A pharmaceutical composition consisting of one or more NPYi's and one or more PDEi's, optionally admixed with a pharmaceutically acceptable carrier, diluent or excipient.

40. (Withdrawn) A pharmaceutical composition according to claim 39 wherein said NPYi is a NPY Y1i.

41. (Withdrawn) A pharmaceutical composition according to claim 40 wherein said NPY Y1i is highly selective for NPY Y1 receptors associated with genitalia.

42. (Withdrawn) A pharmaceutical composition according to claim 41 wherein said PDEi is a PDE5i.

43. (Withdrawn) A pharmaceutical composition according to claim 42 wherein the composition is administered by mouth.

44. (Cancelled).